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10/674,209	09/29/2003	Shoji Iwasa	O11.2B-11333-US01	2521

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VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

MARCHESCHI, MICHAEL A

ART UNIT	PAPER NUMBER
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1755

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/674,209

Applicant(s)

IWASA, SHOJI

Examiner

Michael A. Marcheschi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 6-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Applicant's election without traverse of Group I in the reply filed on 4/25/05 is acknowledged.

**Applicant is required to cancel the non elected claims.**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as obvious over Tsuchiya et al. (872) for the same reasons set forth in the previous office action which are incorporated herein by reference.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as obvious over Inoue et al. (652) in view of Tsaur for the same reasons set forth in the previous office action which are incorporated herein by reference.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as obvious over Inoue et al. (672) in view of Tsaur for the same reasons set forth in the previous office action which are incorporated herein by reference.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as obvious over Sasaki in view of Tsaur for the same reasons set forth in the previous office action which are incorporated herein by reference.

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all the claims of copending

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Application No. 10/673,779 for the same reasons set forth in the previous office action which are incorporated herein by reference.

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/673,767 for the same reasons set forth in the previous office action which are incorporated herein by reference.

Applicant's arguments filed 4/25/05 have been fully considered but they are not persuasive.

In sections 2b-2d of the response, applicant argue that the composition of the present invention provides synergistic results with respect to the action of HEC and PEO and the assumption of obviousness does not apply to situations that produces unexpected results. The examiner acknowledges the results defined in the examples and acknowledges that some synergism and unexpected results might exist over PEO and HEC alone, but only for compositions that contain HEC and PEO in specific amounts. However, the examiner does not agree that the examples show synergistic results for all of the possible combinations of HEC and PEO defined in the claims. The claims define a composition comprising a combination of PEO and HEC, wherein the PEO is present in a defined range (more than 0.005-less than 0.5% PEO). The independent claim, at least, however, fails to define any amount of HEC. The examples, which define specific values for both the PEO and HEC, are argued as showing synergistic and/or unexpected results with respect to the claimed composition. Since the independent claim at least is silent with respect to any amount of HEC, how can one show synergism for a

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combination of HEC and PEO when the examples, which are used for the bases for showing synergism and/or unexpected results, only use specific amounts for the PEO and the HEC components? Applicant apparently argues in sections 2e-2f that the examples illustrate that the claims need not list specific amounts because all possible mixtures of HEC and PEO will produce some synergistic results. The examiner is unclear as to how this statement can be made because to make a jump that all concentration of HEC used with PEO (amount of PEO only defined in the independent claim) will provide synergistic results (without any evidence to support this) is improper. It would appear that this statement is an opinion of applicant and is not substantiated by any evidence to support it, thus any argument based on this is not persuasive absent sufficient evidence. In addition, applicant argues that a significant number of values outside of a claimed range need not be listed because all possible mixtures of HEC and PEO in the claimed range will produce some synergism. How can this assumption be made if the independent claim does not define an amount for the HEC component (claim does not define any range for the mixture). In view of this, the independent claim lacks a claimed range for both HEC and PEO, thus how can any arguments be made of the claimed range if the claim does not fully define a claimed range for HEC and PEO? As an example, all of applicants examples show a HEC concentration of at most 1%, and therefore how can one justify synergism for a composition that can contain a much larger concentration of HEC. For instance, Inoue et al. (672) can use the water soluble polymer in an amount of at most 10% , thus if PEO is used at 0.5%, the HEC can be 9.5% (obvious combination). In other words, how will a mixture that contains at most 0.5% HEC show any synergism (when used with PEO ) for a composition that can contain 9.5% HEC, as in the case of Inoue et al. (672)? Applicants have not sufficiently

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compared the claimed invention with that of the references, especially in view of the fact that the independent claim defines no amount for the HEC component. In addition, to the extent that the examples and comparative examples include HEC and PEO, as defined by the claims, the examples are only limited to PEO and HEC having a specific molecular weight and are only limited to ammonia, as the alkaline component, thus how can a comparison be used to establish criticality of the claims when the claimed HEC and PEO do not require any molecular weight and the claims do not define the specific alkaline compound, as used in the examples. It would appear that the claims are much broader in scope than the examples and therefore said examples are not commensurate in scope with the claims. As a further comment, the examples are only limited to specific amounts for HEC in combination with specific amounts for PEO, thus how can these examples which use specific combinations be used to show criticality for a composition, as in claim 1, wherein the combination of PEO and HEC are not limited (i.e. the broad interpretation of the independent claim 1 includes an extremely large permeation of possible combinations which is clearly much broader than the examples and comparative example combinations defined). In addition, the tables use specific proportions of components (components of a specific molecular weight) and the instant claims do not define any proportions and/or molecular weights. In view of this, how can the tables, which use specific amounts and molecular weights for the individual components be used to establish criticality (synergism) for a composition (as in the independent claim) which does not require any specific amounts and/or molecular weights? Will all molecular weight materials produce the same results? To make a jump that all molecular weight water soluble polymers and all alkaline components will provide similar results (without any evidence to the contrary) is improper.

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The examiner is aware that one can reasonably extrapolate the data in table(s) to establish a trend in the results however, the tables do not define a sufficient number of points (especially in terms of the molecular weight) to clearly establish a trend in the results. In view of the above, the evidence of unexpected results is not clear and convincing. Evidence of unexpected results must be clear and convincing. *In re Lohr* 137 USPQ 548. Evidence of unexpected results must be commensurate in scope with the subject matter claimed. *In re Linder* 173 USPQ 356. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside (i.e. as well as the upper and lower limits) the claimed range to show the criticality of the claimed range. *In re Hill* 284 F.2d 955, 128 USPO 197 (CCPA 1960).

Referring to the arguments based on the references (sections 2(g)-2(j)), applicant argues that the references do not disclose the HEC and PEO for reducing haze. The use of the components are immaterial because they are still known to be used, irrespective of the function, the combination being obvious for the reasons defined in the previous office action which applicants have not persuasively argued. In addition applicant argues the use of the claimed composition but the intended use provides no patentable weight to a composition. Finally, applicant appears to be arguing that no motivation is apparent for the claimed combination. This is not persuasive because the motivation is in ***In re Kerkhoven* 205 USPQ 1069**. In addition, at least one reference states that “at least one water soluble polymer is used” (i.e. making a combination apparent).

With respect to the arguments based on the ODP rejections (section 3), applicant state that three separate cases were filed to avoid the issuance of a restriction. In response, this does

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not preclude any ODP rejections from being made. Applicant appears to argue that the copending claims only define a water soluble polymer and say nothing about mixing HEC and PEO. The examiner disagrees because claim 8 of 10/673,767 and claim 7 of 10/673,779 implies that mixtures of HEC and PEO can be used (i.e. at least one). With respect to any argument based on superior results, thus is not persuasive for the reasons defined above with respect to the examiners answer to sections 2(b)-2(f) of the response.

With respect to the arguments based on the supplemental examples and the declaration filed 4/25/05 this is not persuasive for the reasons defined above with respect to the examiners answer to sections 2(b)-2(f) of the response. At most the examples might show synergistic and/or unexpected results for the specific compositions in the examples, but not for the broad composition, as claimed in the independent claim, at least. In addition, the examples employ specific molecular weight materials, as well as, specific alkaline component, thus how can one establish the argued results when the claims do not require the defined molecular weights and specific alkaline components? Will all molecular weight materials provide the same synergism and will all alkaline components provide the same argued unexpected results?

Assuming arguendo about the molecular weights and alkaline component, at most, synergism and criticality might be shown for the specific HEC and PEO mixture defined in claim 3.

In view of the teachings as set forth above, it is still the examiners position that the references reasonably teach or suggest the limitations of the rejected claims.



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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**A reference is good not only for what it teaches but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ 2d 1235, 1236 (CAFC 1989); *In re Bode* USPQ 12; *In re Lamberti* 192 USPQ 278; *In re Bozek* 163 USPQ 545, 549 (CCPA 1969); *In re Van Mater* 144 USPQ 421; *In re Jacoby* 135 USPQ 317; *In re LeGrice* 133 USPQ 365; *In re Preda* 159 USPQ 342 (CCPA 1968). In addition, "A reference can be used for all it realistically teaches and is not limited to the disclosure in its preferred embodiments" See *In re Van Marter*, 144 USPQ 421.**

**A generic disclosure renders a claimed species prima facie obvious. *Ex parte George* 21 USPQ 2d 1057, 1060 (BPAI 1991); *In re Woodruff* 16 USPQ 2d 1934; *Merk & Co. v. Biocraft Lab. Inc.* 10 USPQ 2d 1843 (Fed. Cir. 1983); *In re Susi* 169 USPQ 423 (CCPA 1971).**

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The subject matter as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the overlapping portion of the range disclosed by the reference because overlapping ranges have been held to be a prima facie case of obviousness, see *In re Malagari*, 182 U.S.P.Q. 549; *In re Wertheim* 191 USPQ 90 (CCPA 1976).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Marcheschi whose telephone number is (571) 272-1374. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on (571) 272-1233. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/05  
MM

Michael A Marcheschi  
Primary Examiner  
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